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Science & Technology
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6/11/2003

TO: See Distribution List

FROM: Martha Lamont, Director
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SUBJECT: Microbiological Data Program Plan, June through December, 2003

This Program Plan serves as the current Statement of Work for the period June through December 2003 for each State participating in the Microbiological Data Program (MDP). This document also stipulates work assignments for the Federal facility participating in MDP.

I. ADMINISTRATIVE UPDATES

Program participants are reminded to keep MDP management informed of any critical equipment purchases, staffing issues, or expected increases in rent (e.g., due to laboratory or office renovation/relocation). This information is required under the terms of the MDP Cooperative Agreements (Section II, Responsibilities) between USDA and participating States.

A. Personnel

Dr. Shanker Reddy and Donna Dickriede, microbiologists, joined MPO in May, 2003 and will share MDP responsibilities with Terry Councell. Sampling concerns should be directed to Patricia Moe and Sharon Williams; QA concerns should be directed to Diana Haynes. Dr. Michael Doyle, Regents Professor and Director, Center for Food Safety, University of Georgia, Athens, GA has been proposed to serve as a consultant to MDP. Therese Murtagh has returned to her position with the USDA Office of Pest Management Policy. She was detailed with the MPO for a 1-year period.

B. Financial/Cooperative Agreements

The Fiscal Year 2003 (FY03) budget included $6.23 million for MDP, an amount equal to the FY02 budget amount. All MDP FY03 Cooperative Agreements have been issued.

C. MDP Program Meetings

The Federal/State MDP meeting was held on May 15-16, 2003 in Arlington, VA. The next meeting is tentatively scheduled for early December in Sacramento, CA.

The MDP Advisory Committee has been meeting monthly by teleconference; the next call is scheduled for June 19.

Technical Committee

Salmonella BAX Validation: Participating labs have validated the *Salmonella* BAX PCR method for lettuce and celery in a side-by-side comparison using cultural and serological methods. Validation studies for tomatoes and cantaloupe are ongoing. Initiation of BAX as the first step in detection of *Salmonella* in routine samples will be addressed when all BAX validation studies have been completed.

E.coli MPN Method: MPO will pursue having Kevin Vought of the Minnesota Dept. of Agriculture investigate alternative methods that are less labor-intensive than the current serial dilution method for MPN analyses.

Universal Pre-enrichment Broth: MPO is investigating the use of UPB for pre-enrichment medium for current MDP *E. coli* and *Salmonella* methodologies.

Quality Assurance Overview

The MDP QA program covers all aspects of data gathering – from sample collection to data reporting. QA protocols for sampling are designed to protect sample integrity from the time of collection to the time of delivery at the testing facilities. QA protocols for testing comprise all laboratory operations from the time of sample receipt to the time data are reported to MDP's central database which is located in Manassas, Virginia. MDP laboratories guarantee reported results by adherence to strict QA requirements. The QA program is comprised of five elements: 1) Standard Operating Procedures (SOPs); 2) On-Site Reviews; 3) Proficiency Testing; 4) Quality Control (QC) Procedures; and 5) Method Performance and Verification Procedures.

Proficiency Testing Program

Proficiency test samples for MDP are under development by RTech. Proficiency sampling has been on hold while the laboratories complete the BAX validation studies. Proficiency testing of *E. coli* will be conducted later in 2003; scheduling will be determined in consultation with the laboratories.

Standard Operating Procedures (SOPs)

SOP	Responsibility	Status
Admin 01-08	MPO	Issued for comment 05/12/03; split 06 into 06A (MPO) and 06B (lab) and reissued for comment 05/30/03.
MDP-DATA-01 Microbiological Record Keeping and Results Reporting	MPO	Revision 1 effective 4/15/03.
MDP-LABOP-01 Infrared (IR) Thermometer Use	Kurt Mangione New York	Revision 1 effective 4/15/03.
MDP-LABOP-02 Sample Wash Procedures	Cindy Koschmann Wisconsin	Initial procedures combined with LABOP-05 and 06; revision 2 draft to be finalized for signature.
MDP-LABOP-03 Microbiological Media	Gary Husby Washington State	Revision 1 draft reissued for comment 05/28/03.
MDP-LABOP-04 Shipping Microbiological Cultures	MPO	Changed to MDP-SHIP-01 and MDP-SHIP-02; drafts issued for comment 06/06/03.
MDP-LABOP-07 Maintenance of *Salmonella* and *E.coli* Positive Control Cultures with GFP Plasmid	Dan Mills California	To be discussed at 06/19/03 conference call.
MDP-MTH-01 *Escherichia coli* MPN Method	Grace Hall Florida	Revision 2 to be issued for signature upon LABOP-07 finalization.
MDP-MTH-02 *Salmonella* VIDAS Method	Fran Mohnke Michigan	Revision 2 to be issued for signature upon LABOP-07 finalization.
MDP-MTH-03 *Salmonella* Cultural Method	Mary Ann Murphy National Science Laboratory	Revision 1 draft (03) issued for comment 06/12/03.
MDP-DATA-01 Microbiological Data and Results Reporting	MPO	Revision 1 effective 04/15/03.
MDP-DATA-02 Records Retention	MPO	To be developed.
MDP-QA-01 Laboratory Practices and Equipment Preventive Maintenance	Maureta Ott Ohio	Under development; will be split into two SOPs.
MDP-QA-02 Proficiency Test Samples	MPO	To be revised when scheduling is finalized with RTech and MDP laboratories.
MDP-Glossary	MPO	Under development.

D. Electronic Transfer of Data

Legacy RDE Cut-Off Extended to July 1, 2003: The cut-off date for ending use of the legacy Access-based Remote Data Entry (RDE) system was extended from June 1, 2003 to July 1, 2003. This means that the Web-based RDE system should be used for all samples collected after June 30, 2003. This extension will allow time for MPO to fix several glitches in the software, primarily in printed reports.

Reengineered RDE System Architecture: The reengineered RDE system is a centralized system, where all RDE database files and support software will reside in Washington, D.C. and laboratory users will require only an Internet web browser on the front-end. A stand-alone SIF data entry system for laptop/desktop computers and for PDAs (Pocket PCs) was developed to allow the capture of SIF data electronically by sample collectors. The SIF data entry system can also be used by laboratories to perform off-line data entry of paper SIF information that can then be imported into the central RDE system.

New RDE Secure Web Address: RDE users in the laboratories should start using the SSL (Secure Socket Layer) site address to access the system. The SSL address is https://www.ams.usda.gov/rde. The only difference is the addition of the letter "s" following "http". This SSL technology is used to encrypt all data passed between the user's computer and the central web server.

Future RDE System Revisions: The RDE contractor has turned over the source code to MPO and all future system modifications will be programmed by the MPO staff. MPO is maintaining a database of all user change requests, including problems and suggestions received by telephone and e-mail.

II. PROGRAM SAMPLING AND TESTING UPDATES

A. Sampling Changes and Rotations: See the attached 2003 Shipping Charts.

Sampling Deletions: None

Sampling Additions: None

Sampling Continuations: Celery, leaf lettuce, romaine lettuce, tomatoes, and cantaloupe will continue.

B. Testing

Shipping Samples for Further Testing

Shipment of samples to reference labs will continue with the following changes;

E. coli isolates are shipped simultaneously to the ARS laboratory for inclusion in the NARMS database and to the laboratory at Pennsylvania State University (PSU) for antibiotic resistance testing and serotyping.

Salmonella isolates are shipped simultaneously to the ARS laboratory for inclusion in the NARMS database, to the laboratory at Pennsylvania State University (PSU) for antibiotic susceptibility testing and to the University of Pennsylvania for serotyping.

Microorganisms

MDP laboratories will continue to test samples for *E. coli* (quantitative testing) and for *Salmonella* (presence or absence). Testing for *Shigella* will begin after a method has been developed in cooperation with FDA and validated in each laboratory.

C. Future Planning

Development of Testing Procedures for *E. coli* O157:H7

MDP is considering the use of BAX PCR and a specific pre-enrichment broth such as UPB. Positive BAX samples would be enriched by immunomagnetic separation followed by isolation on media such as SMAC and Rainbow Agar. Individual colonies would be sent to Penn State University for serology and susceptibility testing, including acid tolerance.

Development of Testing Procedures for *Shigella*

FDA/CFSAN continues to work on methodology for *Shigella* testing. MDP remains willing to participate in validation studies. MPO is looking at enrichment media for Shigella with the Minnesota Dept. of Agriculture. MDP laboratories will be given progress updates during monthly teleconferences. MDP laboratories may also be asked to participate in method development. When the method is finalized, MDP laboratories in California, Florida, North Carolina, Ohio, the Minnesota Department of Agriculture, FDA, and the Canadian government laboratories will all participate in a validation study. Any testing of *Shigella* will occur after validation studies are completed for *E. coli* O157:H7 BAX-PCR.

If these changes are adopted, the Program Plan will be amended to include the changes. Discussions with the Technical Advisory Committee are being held.

Attachments